Remarks/Arguments:

Claims 1-24 are pending in the application. Claims 1 and 11 are currently amended. No new matter has been added.

Restriction

Claims 4, 5, and 16-24 have been withdrawn from consideration in the Office Action allegedly because Group I and Group II contain the same or a corresponding technical feature and relate to a single general inventive concept under PCT Rules 13.1 and 13.2. Applicants traverse the restriction requirement as contrary to the PCT rules.

The Office Action states, "Claim 1 recites that two different flow tracks are present, yet there is nothing recited in the device of claim 1 that enables this to occur. The only way for two different (independent) flow tracks to be present on the same membrane is for some sort of divider to be present." Office Action pg. 2. Applicants respectfully traverse the rejection.

As is evident from the specification and particularly as shown in the examples, a divider is not necessary to achieve more than one flow track on a single membrane. An adequate amount of a sample is applied to the application zone 5 to induce the liquid to flow in the direction of the absorption region 3 and through the indicator zones 6. See e.g., substitute spec. pg. 20, line 30 to pg. 21, line 2 and pg. 17, lines 21-29. In viewing for instance Figure 1, a first flow track would be running through indicator zones I and VI, a second flow track would be running through indicator zones II and VII, and so on and so forth. Thus, different flow tracks are present on the same membrane. As claimed in claim 5, "the test liquid for any one flow track passes through more than one indicator zone." As claimed in claim 4, "the test liquid for any one flow track flows through not more than one indicator zone." Accordingly, the flow tracks may flow through only one or more than one indicator zone. A divider is not necessary to achieve the desired effect in the claimed invention. Hence, the flow from the application zone through a respective indicator zone or zones to the absorption region represents the flow tracts. See e.g., substitute spec. pg. 8, lines 16-19.

The subject matter is adequately described and shown, and withdrawal of the rejection is respectfully requested. Applicants submit that resolving this issue should clarify the Examiner's concerns with regard to the references cited.

With regard to WO 88/08534 ("May"), Applicants submit May discloses devices with either a plurality of detection zones arranged in series on the porous solid phase or two or more discrete bodies of porous solid phase material (*i.e.*, separate membranes) in parallel. Disclosure of a membrane that has as a feature "at least two different flow tracks which are substantially parallel" is clearly missing from the disclosure of May. May discloses only one flow track on one test strip (a membrane). Further, a simultaneous detection of a plurality of analytes is not possible using May's device due to the existence of a physical barrier between the indicator zones. May requires different analytes to be simultaneously tested only by using different test strips.

May teaches separate strips or sheets arranged in parallel as indicated in the Office Action. Office Action pg. 2. But May does not teach at least two flow tracks present parallel on **one membrane**. Further, May does not teach that "at least two types of indicator particles are used of which at least one type being erythrocytes." Further, May does not teach a device comprising a membrane which "comprises a first indicator zone containing a bonding element for binding the cellularly bound analyte and the membrane comprises a second indicator zone containing a binding element for binding an element contained in plasma." Therefore, the subject-matter of claim 1 is not anticipated by May. It is respectfully requested that the restriction requirement be withdrawn and claims 4 and 5 are permitted to stay for further prosecution.

Because the claimed invention is not anticipated by May, the claims of Group I and Group II contain the same or a corresponding technical feature and, therefore, relate to a single general inventive concept under PCT Rule 13.1. Accordingly, the restriction requirement is improper and should be withdrawn. Applicants respectfully request reconsideration of the requirement.

35 U.S.C. § 112, First Paragraph

Claims 1-3 and 6-15 stand rejected as allegedly failing to comply with the written description requirement. As discussed above, the flow from the application zone through a respective indicator zone or zones to the absorption region represents the flow tracks. See e.g., substitute spec. pg. 8, lines 16-19. These tracks are substantially parallel as required by the placement of the indicator zones. As is shown throughout the specification, in the examples, and drawings, and as described above, it is not necessary for the membrane to include any type

of divider or barrier. Applicants also note there is no recitation of a "membrane" with "an application point." Because the subject matter is adequately described, withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, Second Paragraph

Claims 1-3 and 6-15 stand rejected as allegedly indefinite. Claims 1 and 11 are currently amended. For at least the following reasons, Applicants respectfully submit the aforementioned claims are in allowable form. Applicants submit claim 1 is clear, as described above, with respect to the flow tracks and without the need for any type of divider. The Office Action states claim 1 is vague because it is allegedly unclear if the indicator zones also function as detection zones and due to the term "conjugate pad" in claim 13. It is explicitly stated in the specification, however, that "[t]he bonding reactions between the analyte and the bonding element are detected in the indicator zone." See pg. 8, lines 23 to 24 of the substitute spec. (emphasis added). Further, the conjugate pad recited in claim 13 is merely an exemplary embodiment. The function of a conjugate pad is described clearly on, for example, pg. 11, lines 18-31 and pg. 24, lines 4-18 of the specification.

With respect to claim 3, the Office Action alleges the letters in the claim are unclear. Applicants submit that claim 3 clearly recites "the indicator zones are arranged in a diagonal V-, W-, M-, N-shaped or linear row." One of skill in the art would readily understand these arrangements. See also substitute spec. pg. 9, lines 4-11. Claim 3 is clear and the rejection should be withdrawn.

With respect to claim 12, Applicants submit the sealing element is described throughout the specification and is clear in the Figures. For example, pg. 18, lines 5-19 describe the form and function of the sealing element in detail. Also, Figures 1-11 provide further understanding of the sealing element and, specifically, Figures 1 and 2 showing sealing element 4. Because claim 12 is clear, the rejection should be withdrawn.

35 U.S.C. § 103

Claims 1-3 and 7-15 stand rejected as unpatentable over U.S. Patent No. 7,303,923 ("Hardman") in view of WO 88/08534 ("May") and U.S. Patent No. 4,943,522 ("Eisinger"). Claims 1-3 and 7-15 stand rejected as unpatentable over U.S. Patent No. 5,770,458 ("Klimov")

in view of Eisinger. Claims 1-3, 6-11, and 13-15 stand rejected as unpatentable over U.S. Patent No. 5,559,041 ("Kang") in view of Eisinger. Applicants traverse these rejections.

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in KSR Int'l Co. v. Teleflex, Inc., 550 U.S. _ (2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed. Applicants respectfully submit that the Office has not met its burden in this regard.

Claims 1-3 and 7-15 Hardman in view of May and Eisinger

Applicants submit the references alone or in any reasonable combination do not teach the limitations of claim 1. Claims 1-3 and 7-15 stand rejected as unpatentable over Hardman in view of May and Eisinger. Hardman discloses a device which comprises (a) a substrate comprising (i) a porous material capable of chromatographically transporting a liquid and (ii) one or more test reagents for an assay provided on the porous material; and (b) a water-impermeable coating polymer attached to the porous material so as to define a continuous bibulous compartment. Therefore, the claimed invention differs from Hardman in at least the following aspects:

(a) there is no use of at least two types of indicator particles of which at least one type being erythrocytes in Hardman;

(b) there is no use of two indicator zones on one membrane wherein a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma;

(c) there is no absorption region in Hardman;

(d) the flow tracks in Hardman are not parallel;

(e) a water-impermeable coating polymer as required in Hardman is not needed in the claimed invention; and

(f) there are not at least two different flow tracks present on one membrane in Hardman.

Thus, there is more than one difference between Hardman and the claimed invention.

With particular emphasis on the (d) and (f) discussed above, Hardman discloses a bibulous compartment with a plurality of channels. Hardman requires separate membranes and a physical barrier to separate the channels to detect more than one analyte and describes Y shaped flow tracks. Claim 1 recites in part, however:

> at least one membrane with an application zone for the application of the liquid sample, at least one group of at least two indicator zones, which are able to interact with the analytes, and at least one absorption region which takes up the liquid after having passed the indicator zones; . . . the indicator zones are located between the application zone and the absorption region wherein the flow directions from the application zone through the respective indicator zones of a group towards an absorption region (flow tracks) are substantially parallel and that at least two different flow tracks are present.

As discussed above, dividers or barriers are not necessary for the claimed invention. Thus, Hardman at least does not teach the at least one membrane with at least two different flow tracks which are substantially parallel.

May does not remedy the deficiencies of Hardman. As explained above, May does not teach or suggest a plurality of indication zones arranged in parallel on a single membrane and does not allow for testing of multiple analytes on a single test strip. May discloses a plurality of detection zones, but does not disclose use of at least two types of indicator particles of which at least one type being erythrocytes. May further does not disclose a membrane comprising a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma on the same membrane. May discloses only test strips (more than one membrane) arranged in parallel, but does not disclose one membrane with at least two different flow tracks which are substantially parallel. Thus, even if a skilled person were to combine the teaching of Hardman and May, they would not arrive at the device as claimed.

Further, Eisinger does not remedy the deficiencies of Hardman and May. Eisinger discloses a device and method for detecting blood group antigens. Eisinger does not disclose use of at least two types of indicator particles of which at least one type being erythrocytes, nor does Eisinger disclose a membrane comprising a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma on the same membrane. Thus, a skilled person upon reading Hardman, May, and Eisinger and even combining the teachings thereof would not arrive at the device as claimed. Accordingly, a *prima facie* case of obviousness has not been established, and withdrawal of the rejections is respectfully requested. Applicants submit claim 1 is allowable and claims 2-24 are allowable as dependent thereon for at least the reasons set forth above.

Claims 1-3 and 7-15 Klimov in view of Eisinger

Applicants submit the references alone or in any reasonable combination do not teach the limitations of claim 1. Claims 1-3 and 7-15 stand rejected as unpatentable over Klimov in view of Eisinger. The Office Action sets forth that, Klimov discloses a device comprising a membrane having an application zone, a group of at least two indicator zones, and at least one absorption region. Office Action pg. 8. However, the at least two flow tracks of Klimov are present in the different membranes: one runs in the main membrane and the second permeates into the top membrane. See col. 7, lines 40-44 of Klimov. Whereas in the claimed invention, the at least two flow tracks are present on the same membrane. Additionally, Klimov does not disclose use of at least two types of indicator particles of which at least one type being erythrocytes, nor does Klimov disclose a membrane comprising a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma on the same membrane.

With respect to Eisinger, as set forth in the Office Action, Eisinger discloses a device and method for detecting blood group antigens. Office Action pg. 9. Eisinger teaches reagents for analytes including antigen present on red blood cells. Eisinger teaches a method of blood typing by applying a blood sample to a device having more than one indicator zone, each of which contains a blood typing reagent. Eisinger does not teach, however, the simultaneous determination of cellular and plasma parameters. Eisinger also does not disclose use of at least two types of indicator particles of which at least one types being erthrocytes, nor does Eisinger

disclose a membrane comprising a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma on the same membrane. Therefore, a skilled person at the time of the invention, even in combining the teachings of Klimov and Eisinger, would not reach the device as claimed. Accordingly, a *prima facie* case of obviousness has not been established, and withdrawal of the rejections is respectfully requested. Applicants submit claim 1 is allowable and claims 2-24 are allowable as dependent thereon for at least the reasons set forth above.

Claims 1-3, 6-11, and 13-15 Kang in view of Eisinger

Applicants submit the references alone or in any reasonable combination do not teach the limitations of claim 1. Claims 1-3, 6-11, and 13-15 stand rejected over Kang in view of Eisinger. Kang discloses an immunochemical assay device comprising a base membrane with (i) a reservoir pad; (ii) a wicking membrane with two indicator zones; and (iii) at least one filter zone. The filter element disclosed in Kang is used to trap unwanted components in the fluid sample, especially as a controlled cell lysing system. See col. 5, line 54 to col. 6, line 4 of Kang. Kang discloses explicitly, for example, "in an immunstatus assay performed on a sample of whole blood it is an advantageous to select as the second filter element a membrane which would maintain the integrity of whole blood cells while serum migrates through. This prevents the discoloration associated with blood cell lysis from spreading into the assay indicia zone." Col. 5, line 65 to col. 6, line 4 of Kang. Therefore, Kang actually teaches that the device disclosed is **not suitable** for determination of a plurality of analytes, wherein at least one analyte is a cellularly bonded analyte. Accordingly, a person skilled in the art would not consider using the device of Kang in the claimed invention for simultaneous and qualitative or quantitative determination of a plurality of analytes, wherein at least one analyte is a cellularly bonded analyte.

As discussed above, Eisinger does not teach the simultaneous determination of cellular and plasma parameters. Eisinger does not disclose use of at least two types of indicator particles of which at least one types being erthrocytes, nor does Eisinger disclose a membrane comprising a first indicator zone contains a bonding element for binding a cellularly bound analyte and a second indicator zone containing a bonding element for binding an analyte contained in plasma on the same membrane. Therefore, a skilled person at the time of the

invention, even combining the teachings of Kang and Eisinger, would not reach the device as claimed. Accordingly, a *prima facie* case of obviousness has not been established, and withdrawal of the rejections is respectfully requested. Applicants submit claim 1 is allowable and claims 2-24 are allowable as dependent thereon for at least the reasons set forth above.

Double Patenting

Claims 1-5 and 7-15 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-9 of co-pending U.S. Application No. 10/563,659. Applicants note the rejection and will address the rejection upon the indication of allowable subject matter. Applicants request that the rejection be held in abeyance.

Conclusion

For all of the foregoing reasons, Applicants respectfully request reconsideration and allowance of the claims. Applicants invite the examiner to contact their undersigned representative if it appears that this may expedite examination.

Respectfully submitted,

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